

REMARKS

Claims 1-35 were pending but subject to restriction such that only claims 1-25 are being examined. In connection with a Request for Continued Examination (RCE) filed concurrently herewith, Applicants now wish to elect invention of Group IV (claims 30-35) and thus have cancelled claims 1-29. Further, Applicants have amended claims 30, and 33-35, cancelled claim 32 and added new claims 36-37. Accordingly, claims 30, 31 and 33-37 are now pending.

Support for amended claims 30 and 33-35 and new claims 36-37 may be found in the claims and specification as originally filed. Accordingly, these changes do not involve new matter and Applicants respectfully request entry of these changes.

Amendment to claims 33 and 35 merely involves correcting claim dependencies.

Support for amended claim 30 may be found in the specification as originally filed at page 14, lines 4-15; page 32, lines 7-9; and originally filed claims 1, 2 and 18.

Support for amended claim 34 may be found in the specification as originally filed at page 37, line 17 and line 25; page 55, lines 13-14; and originally filed claims 23 and 28.

Support for new claim 36 may be found in the specification as originally filed at page 31, lines 19-22 and page 37, lines 10-12.

Support for new claim 37 may be found in the specification as originally filed at page 32, lines 7-11.

Entry of these amendments and the foregoing remarks in the file of the above-captioned patent application is respectfully requested.

ITEMS 1-5: CLAIMS STATUS

At page 2 of the Office Action, the Office has indicated that claims 1-35 are pending, claims 1-25 are being examined and claims 26-35 are withdrawn as being drawn to a non-elected invention.

As indicated above, Applicants have now elected invention of Group IV and accordingly claims 30-31 and 33-37 are currently pending.

ITEM 6: WITHDRAWN REJECTION

At page 2 of the Office Action, the Office has indicated that provisional rejection of claims 1-16 and 18-25 under 35 U.S.C. §101 as claiming the same invention as claims 1-16 and 18-25 of co-pending application U.S. Serial No. 10/895.183 is withdrawn in view of amendments to claims filed on October 23, 2006 in the co-pending application U.S. Serial No. 10/895.183. No response is due.

ITEMS 7-12: OBJECTIONS

At pages 2-4 of the Office Action, the Office has objected to the specification and claims 20-21 and 23-24 due to informalities.

In compliance with the Office's request, Applicants have amended the specification, *see supra*. Further, Applicants have cancelled claims 20-21 and 23-24 and accordingly, the objection is moot. Applicants respectfully request that the Office withdraw the objection.

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ITEMS 13-14: REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

At page 4 of the Office Action, the Office has rejected claims 1 and 3-25 U.S.C. §112, second paragraph, as allegedly being indefinite in the recitation of “an RG1 polypeptide” and the trademark/trade name “TaxolTM”.

Applicants’ amendments to the claims render the rejection moot, see *supra*. Accordingly, Applicants respectfully request that the Office withdraw the rejection.

ITEMS 15-16: REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

At pages 4-5 of the Office Action, the Office rejects claims 1 and 3-25, under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Additionally, the Office has rejected claims 1, 3-8 and 17-25 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement in the recitation of “Rg1 polypeptide”.

Applicants’ amendments to the claims render the rejection moot, see *supra*. Accordingly, Applicants respectfully request that the Office withdraw the rejection.

ITEMS 17: REJECTION UNDER 35 U.S.C. §102(e)

At pages 6 of the Office Action, the Office has rejected claims 1-2 and 15-17 under 35 U.S.C. §102(e) as allegedly anticipated by Hastings et al., U.S. Patent No. 5,871,969 (hereafter ‘969 patent).

Applicants respectfully disagree. However, Applicants’ amendment render this rejection moot, since the claims now elected are directed to a method of detecting a disease-state in

a subject, wherein the disease-state is associated with expression of an RG1 polypeptide having the amino acid sequence of SEQ ID NO: 2, and wherein the method comprises:

- (a) administering to the subject an immunoconjugate, wherein the immunoconjugate comprises a human antibody or a fragment or a variant thereof that specifically binds to an epitope present the RG1 polypeptide having the amino acid sequence of SEQ ID NO. 2 and wherein the antibody or the fragment or the variant thereof is conjugated to a molecule which is a detectable marker;
- (b) detecting the immunoconjugate, and
- (c) determining if the level of binding of the immunoconjugate is increased as compared with the level of binding detected in disease-free control subjects, an increased level being indicative of a disease state.

THE LEGAL STANDARD FOR NOVELTY

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984). Each and every element of the claimed invention must be disclosed in a single prior art reference in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing the invention in possession of the public. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851, 105 S.Ct. 172 (1984); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576-7 18 USPQ2d 1001 (Fed. Cir. 1991), *clarified, on recons.*, 18 USPQ2d 1896, 1991 U.S.App. LEXIS 8701 (Fed. Cir. 1991). The absence of even a single element from a prior art reference negates anticipation. *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1574, 224 USP1 409, 411 (Fed. Cir. 1984).

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence.

Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill, *Continental Can Co. v. Monsanto*, 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991). “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.”

APPLICANTS HAVE MET THE LEGAL STANDARD FOR NOVELTY

As discussed *supra*, Applicants’ claimed invention is now directed to methods for detecting diseases associated with cells expressing RG1 having the amino acid sequence of SEQ ID NO:2. The cited prior art is not relevant to these claims.

The ‘969 patent teaches nucleic acids encoding human neuronal attachment factor-1 having the sequence shown in Figure 1 of the ‘969 patent. However, the ‘969 patent does not teach an RG1 polypeptide having an amino acid sequence of SEQ ID NO:2 and the steps of the claimed method. Since the prior art references do not teach every aspect of the claimed invention, these references cannot form the basis for an anticipation rejection under §102(e).

ITEM 18: REJECTION UNDER 35 U.S.C. §103(a)

At page 6 of the Office Action, the Office has rejected claims 1-4 and 15-25 under 35 U.S.C. §103(a) as allegedly unpatentable over Ali et al. (US2005/0147556 A1) (hereinafter “Ali ‘556”) in view of Kucherlapati et al. (U.S. Patent No. 6,150,584) and Devaux et al. (U.S. Patent No. 6,824,780).

Applicants respectfully disagree. Again, this rejection is moot in view of the current claims. As discussed *supra*, Applicants claimed invention is directed to methods for detecting diseases associated with cells expressing RG1 having the amino acid sequence of SEQ ID NO:2. The cited prior art is not relevant to these claims.

Ali '556 teaches methods for diagnosing the presence of prostate cancer by analyzing changes in the levels cancer-specific gene (CSG) having the sequence shown in SEQ ID NO:2 of Ali' 556. However, the Ali '556 does not teach an RG1 polypeptide having an amino acid sequence of SEQ ID NO:2 disclosed in the instant application. Further, the Kucherlapati and the Devaux patents also do not teach the missing element, namely, method of detecting a disease-state associated with the expression of an RG1 polypeptide having the amino acid sequence of SEQ ID NO:2. Therefore, combination of Ali with Kucherlapati and Devaux does not result in the claimed invention.

ITEMS 19-22: DOUBLE PATENTING REJECTION

At pages 6-10 of the Office Action, the Office has:

- (i) provisionally rejected claims 1-16 and 18-25 under 35 U.S.C §101 as allegedly claiming the same invention as that of claims 5, 6, 9, 11-15, 18-25, 37-39 and 41-43 of co-pending application U.S. Serial No. 10/895,183;
- (ii) issued a provisional obviousness-type double patenting rejection alleging that claim 17 is unpatentable over claim 17 of co-pending application U.S. Serial No. 10/895,183;
- (iii) issued an obviousness-type double patenting rejection alleging that claims 1-4 and 15-25 are unpatentable over claims 4-9 of U.S. Patent No. 6,682,902 in view of Kucherlapati et al. (U.S. Patent No. 6,150,584) and Devaux et al. (U.S. Patent No. 6,824,780); and

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(iv) issued a provisional obviousness-type double patenting rejection alleging that claims 1-4 and 15-25 are unpatentable over claims 24-29, 31-34 and 44 of co-pending application U.S. Serial No. 10/616,279 in view of Kucherlapati et al. (U.S. Patent No. 6,150,584) and Devaux et al. (U.S. Patent No. 6,824,780).

Applicants respectfully disagree. However, Applicants' amendment render this rejection moot in view of the current claims.

Applicants respectfully point out that in the instant response, Applicants have cancelled claims 1-29. The pending claims are directed to a disease-state associated with the expression of an RG1 polypeptide having the amino acid sequence of SEQ ID NO: 2. Accordingly, the claimed invention is patentably distinct from (i) – (iv) above. Accordingly, Applicants respectfully request that the Office withdraw the rejection.

CONCLUSION

Applicants believe that all grounds for rejection of the claims have been overcome and that the claims pending are now in condition for allowance. Withdrawal of the Patent Office's rejections is requested and prompt allowance of the claims is solicited. If any issues remain in connection with the claim, the Examiner is encouraged to contact the undersigned by telephone to discuss the same.

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If any other fees are necessary in connection with the filing of this Amendment, the Patent Office is authorized to charge any additional fee to Deposit Account No. 50-0306.

Respectfully submitted,

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